IPW Rce 18

PTO/SB/30 (09-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE


# Request For Continued Examination (RCE) Transmittal

Address to:
MS RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

| | |
|---|---|
| *Application Number* | 09/101,518 |
| *Filing Date* | December 21, 1998 |
| *First Named Inventor* | Yi Li |
| *Art Unit* | 1646 |
| *Examiner Name* | M. D. Pak |
| *Attorney Docket Number* | PF218PCT |

**This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.**
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).
   - a. [ ] Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
     - i. [ ] Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
     - ii. [ ] Other _____
   - b. [x] Enclosed
     - i. [x] Amendment/Reply
     - ii. [ ] Affidavit(s)/Declaration(s)
     - iii. [ ] Information Disclosure Statement (IDS)
     - iv. [x] Other Applicant Initiated Interview Request
2. Miscellaneous
   - a. [ ] Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)
   - b. [ ] Other _____
3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
   - a. [x] The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. 08-3425
     - i. [x] RCE fee required under 37 CFR 1.17(e)
     - ii. [ ] Extension of time fee (37 CFR 1.136 and 1.17)
     - iii. [ ] Other _____
   - b. [ ] Check in the amount of $ _____ enclosed
   - c. [ ] Payment by credit card (Form PTO-2038 enclosed)

***SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED***

| | | | |
|---|---|---|---|
| *Name (Print/Type)* | Mark J. Hyman | *Registration No. (Attorney/Agent)* | 46,789 |
| *Signature* | | *Date* | July 1, 2004 |

07/02/2004 CNGUYEN 00000110 083425 09101518
01 FC:1801 770.00 DA

PTO/SB/17 (10-03)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE


# FEE TRANSMITTAL for FY 2004

*Effective 10/01/2003. Patent fees are subject to annual revision.*

☐ Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** ($) 770.00

| Complete if Known | |
|---|---|
| Application Number | 09/101,518 |
| Filing Date | December 21, 1998 |
| First Named Inventor | Yi Li |
| Examiner Name | M. D. Pak |
| Art Unit | 1646 |
| Attorney Docket No. | PF218PCT |

## METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 08-3425

Deposit Account Name: Human Genome Sciences, Inc.

**The Director is authorized to:** *(check all that apply)*

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 1001 | 770 | 2001 | 385 | Utility filing fee | |
| 1002 | 340 | 2002 | 170 | Design filing fee | |
| 1003 | 530 | 2003 | 265 | Plant filing fee | |
| 1004 | 770 | 2004 | 385 | Reissue filing fee | |
| 1005 | 160 | 2005 | 80 | Provisional filing fee | |

**SUBTOTAL (1)** ($) 0.00

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| | | | Extra Claims | | Fee from below | | Fee Paid |
|---|---|---|---|---|---|---|---|
| Total Claims | 100 | -105** = | 0 | x | | = | |
| Independent Claims | 9 | -10** = | 0 | x | | = | |
| Multiple Dependent | | | | | | = | |

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description |
|---|---|---|---|---|
| 1202 | 18 | 2202 | 9 | Claims in excess of 20 |
| 1201 | 86 | 2201 | 43 | Independent claims in excess of 3 |
| 1203 | 290 | 2203 | 145 | Multiple dependent claim, if not paid |
| 1204 | 86 | 2204 | 43 | ** Reissue independent claims over original patent |
| 1205 | 18 | 2205 | 9 | ** Reissue claims in excess of 20 and over original patent |

**SUBTOTAL (2)** ($) 0.00

***or number previously paid, if greater; For Reissues, see above*

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 1051 | 130 | 2051 | 65 | Surcharge – late filing fee or oath | |
| 1052 | 50 | 2052 | 25 | Surcharge – late provisional filing fee or cover sheet. | |
| 1053 | 130 | 1053 | 130 | Non-English specification | |
| 1812 | 2,520 | 1812 | 2,520 | For filing a request for *ex parte* reexamination | |
| 1804 | 920* | 1804 | 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 | 1,840* | 1805 | 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 | 110 | 2251 | 55 | Extension for reply within first month | |
| 1252 | 420 | 2252 | 210 | Extension for reply within second month | |
| 1253 | 950 | 2253 | 475 | Extension for reply within third month | |
| 1254 | 1,480 | 2254 | 740 | Extension for reply within fourth month | |
| 1255 | 2,010 | 2255 | 1,005 | Extension for reply within fifth month | |
| 1401 | 330 | 2401 | 165 | Notice of Appeal | |
| 1402 | 330 | 2402 | 165 | Filing a brief in support of an appeal | |
| 1403 | 290 | 2403 | 145 | Request for oral hearing | |
| 1451 | 1,510 | 1451 | 1,510 | Petition to institute a public use proceeding | |
| 1452 | 110 | 2452 | 55 | Petition to revive – unavoidable | |
| 1453 | 1,330 | 2453 | 665 | Petition to revive - unintentional | |
| 1501 | 1,330 | 2501 | 665 | Utility issue fee (or reissue) | |
| 1502 | 480 | 2502 | 240 | Design issue fee | |
| 1503 | 640 | 2503 | 320 | Plant issue fee | |
| 1460 | 130 | 1460 | 130 | Petitions to the Commissioner | |
| 1807 | 50 | 1807 | 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 | 180 | 1806 | 180 | Submission of Information Disclosure Stmt | |
| 8021 | 40 | 8021 | 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 770 | 2809 | 385 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 | 770 | 2810 | 385 | For each additional invention to be examined (37CFR 1.129(b)) | |
| 1801 | 770 | 2801 | 385 | Request for Continued Examination (RCE) | 770.00 |
| 1802 | 900 | 1802 | 900 | Request for expedited examination of a design application | |
| Other fee (specify) | | | | | |

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3)** ($) 770.00

| SUBMITTED BY | | | | (Complete *(if applicable)*) | |
|---|---|---|---|---|---|
| *Name (Print/Type)* | Mark J. Hyman | *Registration No. (Attorney/Agent)* | 46,789 | *Telephone* | (240) 314-1224 |
| *Signature* | | | | *Date* | July 1, 2004 |

VIA HAND DELIVERY JULY 1, 2004

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:
Li

Docket No.: PF218PCT

Application No.: 09/101,518-Conf. #9737

Filed: December 21, 1998

Group Art Unit: 1646

For: **Human G-Protein Chemokine Receptor HSATU68**

Examiner: M. Pak

**RESPONSE UNDER 37 C.F.R. § 1.111**

**MS Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Final Official Action dated April 6, 2004, Applicant hereby requests the following remarks be entered into the above-identified application. Applicant submits herewith (a) a Fee Transmittal Sheet; (b) a Request for Continued Examination under 37 C.F.R. § 1.114; and (c) an Applicant Initiated Interview Request form (PTOL-413A). Applicant requests that the Examiner contact the undersigned to schedule the requested personal interview prior to the next office action.

Claims 29-128 are pending in the above-captioned application. Claims 33-50, 56-63, 65-73, 79-96, 102-109, 111-119, and 124-128 have been withdrawn from consideration by the Examiner.

## I. Restriction

Pursuant to the Final Official Action mailed April 6, 2004, the Examiner has made final the restriction between Groups 1-13, as defined by the Examiner in Paper No. 12, mailed March 28, 2001, and the further restriction of Groups 14-18, as defined by the Examiner in Paper No. 17, mailed December 17, 2001. In particular, the Examiner alleges that the Declaration of Yi Li (hereinafter "the Declaration") is unpersuasive in that the claims allegedly fail to provide adequate support under 35 U.S.C. §112.

Applicant respectfully disagrees. For the reasons set forth in the amendment and response submitted to the Patent Office on December 16, 2003 (hereinafter "the December 16, 2003 response), Applicant maintains that the restriction requirements are improper. Thus, Applicant respectfully reserves the right to petition from the restriction requirement under 37 C.F.R § 1.144.

## II. Declaration

The Examiner alleges that the Declaration is ineffective to overcome the Marchese et al. reference with regard to lack of unity because the claims fail to provide adequate support under 35 U.S.C. § 112 for certain claims. *See*, page 3, section 5.

In response, the basis for the Examiner's statement that the Declaration is unpersuasive is not clear to Applicant. In particular, Applicant does not understand the Examiner's position that a Declaration antedating a prior art reference can be rendered ineffective by an alleged lack of support by the claims for certain claims under 35 U.S.C. § 112. Applicant requests that the Examiner clarify this position during the requested interview. The Examiner's additional assertions regarding § 112 are addressed in section IV below.

Applicant reiterates that the Declaration shows possession of the same subject matter as the Marchese reference, *e.g.*, the polynucleotide sequence of claim 1, prior to the publication date of that reference. Thus, as stated in Applicant's response dated December 19, 2003, the Declaration clearly provides adequate support to antedate the Marchese reference and for Applicant's assertion that the instant invention possesses a special technical feature over the prior art.

## III. Rejections under 35 U.S.C. § 101 and 112, First Paragraph

The Examiner has maintained the rejection of claims 29-32, 51-55, 64, 74-78, 97-101, 120-123, and 127-128 under 35 U.S.C. § 101 for alleged lack of utility. More particularly, the Examiner contends that

> It is only with the post filing date reference that one skilled in the art is aware of the treatment of tumor with the receptor which was previous to the post filing date publication only known as an orphan receptor. ... Furthermore, at the filing date of the application, the specification lists many different diseases on pages 5 and 22 which have no nexus to treatment with the claimed receptor.

Page 3-4, section 6, third paragraph.

Applicant respectfully disagrees, and traverses this rejection.

Applicant reiterates that the proper legal standard to judge utility rests on whether one of skill in the art, upon reading the entire specification, would find the asserted utilities for the claimed invention an "inherently unbelievable undertaking or involve implausible scientific principles," regardless of whether or not further research is required. *Nelson v. Bowler*, 626 F.2d 853, 857 (C.C.P.A. 1980). Thus, for the reasons set forth in the December 16, 2003, response, the specification teaches the specific, substantial, and credible asserted utility that provides the nexus that the Examiner contends is lacking.

For example, the specification clearly teaches that the polypeptide of the invention is a novel member of the chemokine receptor family. In addition, the specification describes how to make and use antibodies that specifically bind the polypeptide of the invention for the diagnosis and/or treatment of tumors, such as leukemia. (*See*, December 16, 2003 response, paragraph spanning pages 19-20). Applicant has also submitted post-filing date reference, Lasagni *et al*, which fully corroborates the assertions made in the specification. In particular, Lasagni *et al.* describe the polypeptide of the instant invention and provide data corroborating Applicant's assertion that the polypeptide, and thus antibodies that specifically bind thereto, would be useful in the diagnosis and/or treatment of tumors. (*See*, December 16, 2003 response, page 20, second paragraph to page 21, first paragraph).

Thus, Applicant maintains that a skilled artisan would find the specification's assertions that the antibodies of the invention have uses, for example, in the diagnosis and/or treatment of tumors, such as leukemia, to be specific, substantial, and credible based on the totality of the evidence presented in the December 16, 2003 response. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. § 101 be reconsidered and withdrawn.

The Examiner has also rejected claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123, and 127-128 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement based on the alleged lack of utility. For the reasons set forth in the December 16, 2003 response and above, Applicant maintains that the instant invention complies with the utility requirements of 35 U.S.C. § 101. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

## IV. Rejections under 35 U.S.C. § 112, First Paragraph

The Examiner has maintained the rejection of claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123, and 127-128 under 35 U.S.C. § 112, first paragraph for alleged lack of written description. More particularly, the Examiner asserts that:

> one of skilled in the art cannot envision the full genus of antibodies which bind variants whose structure is not known or other variant proteins with different function from SEQ ID NO:2 taught in the specification because the term "comprising" encompass structures which is not part of SEQ ID NO:2

See, page 5, section 7, third paragraph.

Applicant respectfully disagrees and traverses this rejection.

Applicant notes that the Examiner has alleged that the claims at issue contain the open-ended "comprising" and "variant" language. However, the claims were amended in the December 16, 2003 response to remove such language, leaving only closed language, *e.g.*, "a protein whose sequence consists of amino acid residues 1 to 415 of SEQ ID NO:2." (*See* December 16, 2003 response, page 26, Section IV, second paragraph). No "variant" limitations (*e.g.,* percent identity) are present in the pending claims. Therefore, in light of this amendment and the arguments set forth in the December 16, 2003, response, Applicants contend that the instant claims are adequately described by the specification as filed. Should the Examiner not agree, Applicants respectfully request that the Examiner clearly explain with particularity the alleged deficiencies in the language of the pending claims.

Accordingly, Applicant respectfully requests that the rejection of the claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123, and 127-128 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

### *Conclusion*

Applicant respectfully requests that the above-made remarks and amendments be entered and made of record in the file history of the instant application. In view of the foregoing remarks, Applicant believes that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below to schedule the requested Personal Interview. If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension

of time under 37 C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: July 1, 2004

Respectfully submitted,

By _____

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Rockville, Maryland 20850
(240) 314-1224

KKH/MJH/KC/lcc